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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,154	03/07/2002	Craig A. Rosen	PC009C1	7351

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,154	ROSEN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, 14, and 21; drawn to polynucleotides and compositions containing same, classified in class 536, subclass 23.1, and class 435, subclasses 243, 320.1, 325, and 440. If this group is elected, then the below sequence election requirement also is required.

II. Claims 11, 12, and 16; drawn to polypeptides, classified in class 530, subclasses 300 and 350. If this group is elected, then the below sequence election requirement also is required.

III. Claim 13, drawn to an antibody, classified in class 530, subclass 387.1. If this group is elected, then the below sequence election requirement also is required.

IV. Claim 15, drawn to methods of expression of a polypeptide, classified in class 435, subclass 69.1. If this group is elected, then the below sequence election requirement also is required.

V. Claim 17, drawn to methods for preventing, treating, or ameliorating a medical condition with a polynucleotide, classified in class 514, subclass 44. If this group is elected, then the below sequence election requirement also is required.

VI. Claim 18, drawn to drawn to methods of diagnosing based on polynucleotide mutation detection, classified in class 435, subclass 6. If this group is elected, then the below sequence election requirement also is required.

VII. Claim 19, drawn to methods of diagnosing based on polypeptide expression detection, classified in class 435, subclass 7.1. If this group is elected, then the below sequence election requirement also is required.

VIII. Claims 20 and 23, drawn to methods of identifying a polypeptide-binding partner and said binding partner composition, classified in class 436, subclass 501. If this group is elected, then the below sequence election requirement also is required.

IX. Claim 22, drawn to drawn to a method of identifying an activity of a protein in a cell, classified in class 435, subclass 4. If this group is elected, then the below sequence election requirement also is required.

X. Claim 24, drawn to methods for preventing, treating, or ameliorating a medical condition with a polypeptide, classified in class 514, subclasses 2. If this group is elected, then the below sequence election requirement also is required.

SEQUENCE ELECTION REQUIREMENT APPLICABLE TO ALL GROUPS

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect one (1) nucleic acid sequence (See M.P.E.P. § 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a specie election requirement.

M.P.E.P. § 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such

> nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that one (1) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of one (1) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

The inventions are distinct, each from the other because:

The inventions of Groups (I, IV, V, and VI); Groups (II, VII, VIII, IX, and X); and Group III are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups (II, VII, VIII, IX, and X) the critical feature is a polypeptide; for Groups (I, IV, V, and VI) the critical feature is nucleic acid; and for Group III the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups II, etc. to be directed as to its synthesis by a polynucleotide of Groups I, etc., however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, IV, V, and VI); (II,

VII, VIII, IX, and X); and (III) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups IV, V, and VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups IV, V, and VI. One use is directed to polypeptide expression (Group IV) and the others to treatment or diagnosis via nucleic acid binding reactions (Groups V and VI, respectively). Alternatively, the nucleic acids of Group I can be used in nucleic acid preparatory methods such as PCR etc. which is also a clearly distinct usage of such nucleic acids.

The inventions of Group IV, V, and VI are unrelated. These inventions are drawn to separate and distinct methods that require different steps and lead to different outcomes.

The inventions of Group II and Groups VII, VIII, IX, and X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group II can be used in the distinct processes of the inventions of Group VII for diagnosis or in the distinct methods of Groups VIII (binding partner identification), IX (activity identification), or X (treatment etc.), or, alternatively, for substrate processing which would be

available for an enzymatic activity or for affinity purification if the protein is only a binding protein.

The inventions of Groups VII, VIII, IX, and X are unrelated. These inventions are drawn to separate and distinct methods that require different steps and lead to different outcomes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

INVENTORSHIP AMENDMENT

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Lori A. Clow
AU 1631

MARJORIE MORAN
PATENT EXAMINER